

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.: 10/568,201 Confirmation No. 7816
Applicants: Miles et al.
Filed: September 20, 2006
Title: BONE SUBSTITUTE MATERIAL
Art Unit: 1794
Examiner: Vo, Hai
Docket No.: 107687.00013

Mail Stop: Amendment

Commissioner for Patents

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SUPPLEMENTAL RESPONSE TO RESTRICTION REQUIREMENT

Dear Sir

In response to the communication from the Examiner dated February 4, 2009, having a deadline for response expiring March 4, 2009, and further to a telephonic conference on March 13, 2009, where the Examiner extended the courtesy of allowing Applicants to modify their election, Applicants hereby withdraw the election of Group III and elect the invention of group II, claims 14-19, with traverse. The pending application is an application under 35 U.S.C. 371, which requires PCT Rule 13.1 and 13.2 to be applied. In the International Search Report dated December 3, 2004, no lack of unity of invention was found. Indeed, the International Search Authority identified a single reference, WO 03/026714, which was applied to claims 1-8, 10-14, 15, 17-19, 20, 22, 25, 26-28, 30-39 and 51, which includes claims in groups I, II, III and V. Other references were found by the International Search Authority that were applied to claims in group IV, although it is noted that the claims of group VI were not searched as allegedly being directed to subject matter not searched by the relevant search authority. As such, a search of the inventions of at least groups I-V has *already been performed*. The absence of any indication of a lack of unity of invention in the International Search Report and the performance of a search by the International Search Authority clearly demonstrates that the claims relate to a single general

inventive concept under PCT Rule 13.1 and do not lack the same or corresponding special technical feature under PCT Rule 13.2.

Furthermore, the reasons provided by the Examiner for asserting lack of unity of invention fail to show a lack of unity of invention. Indeed, the Examiner admits that all of the groups are directed to an article and a process useful in the general field of bone substitute material. Furthermore, unity of invention should be considered in accordance with the PCT International Search and Preliminary Examination Guidelines, per MPEP 1893.03(d). Paragraph 10.3 of those guidelines is instructive:

10.03 Lack of unity of invention may be directly evident “a priori,” that is, before considering the claims in relation to any prior art, or may only become apparent “a posteriori,” that is, after taking the prior art into consideration. For example, independent claims to A + X, A + Y, X + Y can be said to lack unity a priori as there is no subject matter common to all claims. In the case of independent claims to A + X and A + Y, unity of invention is present a priori as A is common to both claims. However, if it can be established that A is known, there is lack of unity a posteriori, since A (be it a single feature or a group of features) is not a technical feature that defines a contribution over the prior art.

The reasons for finding lack of unity of invention set forth by the Examiner are contrary to these guidelines, as they essentially state that claims A + X and A + Y lack unity of invention because one group of claims includes limitation X and another group of claims includes limitation Y, whereas the PCT guidelines state that unity of invention is present a priori. The test for finding a lack of unity of invention is not to find claim elements that are not common to all claims, but to show that all claims lack a common element.

In this regard, the Examiner further asserts that “Claim 20 is anticipated or obvious over WO 03/026714.” However, numerous claims from different groups were alleged to be anticipated or obvious over that reference in the International Search Report, which is not an examination of the claims and which does not establish that the claims are in fact anticipated or obvious. Furthermore, there is a common feature to all claims that is not disclosed in WO 03/026714. Consider claim 1, which includes “sintering the ceramic slip to form a bone substitute material that is approximately a **positive image** of the distorted foam material.” WO 03/026714 fails to disclose sintering the ceramic slip to form a bone substitute material that is approximately a positive image of the distorted foam material, and in fact, the terms “positive,” “image” and “positive image” are not used anywhere in WO 03/026714 (it is noted that the term “positively influence” is used in an unrelated manner). Likewise, claim 14 includes “a porous

sintered ceramic having approximately the form of a *positive image* of an open celled foam material.” Claim 20 includes “sintering the ceramic clip to form a granular bone substitute material in which the granules are approximately *positive images* of the pieces of foam material.” Claim 40 includes “a multiplicity of granules of a porous sintered ceramic, each granule having approximately the form of a *positive image* of an open celled foam material.” Claim 51 includes “a bone substitute material of a porous sintered ceramic having approximately the form of a *positive image* of an open celled foam material.” Claim 52 includes “a bone substitute material that is approximately the in the form of a *positive image* of an open celled foam material.” The failure of WO 03/026714 to make mention of the terms “positive,” “image” or “positive image” rebuts the assertion that there is no common feature in the claims that is not a technical feature that defines a contribution over the prior art, as the common feature to all claims is missing in the art relied upon by the Examiner.

Therefore, withdrawal of the restriction requirement is requested for these reasons.

Dated: March 17, 2009

Respectfully submitted,

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